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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,616	MENEGATTI ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 8-17* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 24 Jun 2009, in which claims 1 and 13 are amended to change the scope and breadth of the claim; claims 3, 4 and 13 are amended to change the language of the claim and new claim 17 is added.

This application is the national stage entry of PCT/EP04/11236, filed 08 Oct 2004; and claims benefit of foreign priority document ITALY MI2003A002019, filed 17 Oct 2003. An English language translation of this foreign priority document is made of record and the claim of foreign priority is perfected.

Claims 1, 3-6 and 8-17 are pending in the current application.

Rejections Withdrawn

Applicant's Amendment, filed 24 Jun 2009, with respect to claims 14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite has been fully considered and is persuasive, as amended claim 1 does recites "comprising a retinoid as active ingredient", therefore there is sufficient antecedent basis for the limitation of claim 14.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 24 Jun 2009, with respect to claims 1, 3-5 and 8-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al. (US Patent

Application Publication 2005/0031547, filed 28 Apr 2004, cited in PTO-892) in view of Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record) has been fully considered and is persuasive with regard to claims 1, 4-5 and 8-16, as an English language translation of the foreign priority document is made of record and the claim of foreign priority is perfected and relied upon to overcome the intervening reference Tamarkin et al., and Friedman et al. alone does not teach or fairly suggest all limitations of the claims. However, foreign priority document ITALY MI2003A002019 recites at, for example, page 5, line 25 only support for alkyl esters of C_{10}-C_{22} fatty acids. Therefore the full scope of claim 3 is not disclosed in foreign priority document ITALY MI2003A002019.

This rejection with regard to claims 1, 4-5 and 8-16 has been **withdrawn**. This rejection of claim 3 is reiterated as below.

Applicant's Amendment, filed 24 Jun 2009, with respect to claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al. (US Patent Application Publication 2005/0031547, filed 28 Apr 2004, cited in PTO-892) in view of Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record) and further in view of Bonda (US Patent 6,551,605, issued 22 Apr 2003, of record) has been fully considered and is persuasive, as English language translation of the foreign priority document is made of record and the claim of foreign priority is perfected and relied upon to overcome the intervening reference Tamarkin et al., and Friedman et al. in view of Bonda alone does not teach or fairly suggest all limitations of the claims.

This rejection has been **withdrawn**.

Claim Objections

Claim 10 is objected to because of the following informalities: claim 10 at line 2 recites a-tocopherol. This should appear as α-tocopherol. Appropriate correction is required.

The following are new grounds rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended Claims 1, 3-6 and 8-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “the ratio of molar water concentration to molar lecithin concentration (W/lec) is 3". Upon further review of the language as claimed this renders the claim unclear because it is unclear if the ratio is limited to soy lecithin or if this includes phosphatidylcholine. While lecithin is can be used synonymous with pure phosphatidylcholine, it may also mean a mixture with other fatty substances. The specification at page 8 implies the term lecithin may be used to describe phosphatidylcholine. However, because claim 1 explicitly recites both soy lecithin and phosphatidylcholine as the phospholipid emulsifier at lines 7-8, it is unclear whether the

term “lecithin” within the context of claim 1 means soy lecithin or phosphatidylcholine. Claims 3-6 and 8-17 depend from claim 1 and incorporate all limitations therein.

Claim 8 recites "HA derivatives up to the 4th degree of sulphation” at line 11 and “inner esters of HA” at line 12. Upon further review of the language as claimed and in view of new claim 17 the phrase "HA derivatives up to the 4th degree of sulphation” renders the claim indefinite because it is unclear what the metes and bounds of the HA derivative is. The term "derivative" encompasses any possible compound that can be theoretically made from any other compound, in the instant case any possible compound that can be theoretically made from HA. The specification recites O-sulphated HA up to the 4th degree of sulphation at page 6, lines 20-25, however this limitation is not found in the claim. The term "inner ester" of HA renders the claim indefinite because it is unclear what the metes and bounds of the HA ester is. The specification at page 6, lines 20-25 provides adequate guidance that one definition of “inner ester” is auto-crosslinked HA, however this definition is not so well established in the art that it precludes the interpretation of any possible ester wherein the ester is not at the terminal sugar moieties of the HA, but rather at the “inner” sugar moieties. Because adequate guidance for the definition conveyed to one of skill in the art is provided at page 6, lines 20-25, amendment to recite the definition “auto-crosslinked HA” would not introduce new matter.

New claim 17 encompasses the method of claim 13 wherein the solution is required to comprise hyaluronic acid derivatives. The term “derivative” renders claim 17 indefinite because the term "derivative" encompasses any possible compound that can

be theoretically made from any other compound, in the instant case any possible compound that can be theoretically made from HA. Upon further review of the language of the claims and in view of claim 8 wherein the microemulsion further comprises a specific derivative of hyaluronic acid, it is unclear if the hyaluronic acid derivative recited in claim 17 is limited to the making the sodium hyaluronate recited in claim 1 or the specific derivative of hyaluronic acid recited in claim 8. Therefore one of skill in the art would not be readily apprised of the metes and bounds of the invention as claimed.

The following modified grounds of rejection are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al. (US Patent Application Publication 2005/0031547, filed 28 Apr 2004, cited in PTO-892) in view of Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record).

Tamarkin et al. teaches oleaginous emulsions comprising a hydrophobic solvent, surface active agents at a concentration of less than about 10% by weight, and an active agent present at effective concentrations (page 1, paragraphs 13-17). Tamarkin et al. teaches said oleaginous emulsions having less than about 10% by weight water (page 1, paragraph 20). Tamarkin et al. teaches said surface active agents produce oil-in-water microemulsions (page 6, paragraph 118) and said surface active agents consist of the phospholipid phosphatidylcholine (page 7, paragraph 127). Tamarkin et al. teaches the solvent includes the alkyl ester fatty acid isopropyl palmitate (page 5, paragraph 92). Tamarkin et al. teaches said active agent includes the class of retinoids for example isotretinoin (page 12, paragraph 211). Tamarkin et al. teaches the microemulsion includes the antioxidant alpha-tocopherol (page 14, paragraph 238) and embodiments comprising the preservative parabens (page 18, paragraph 331 and paragraph 347 spanning pages 19-20). Tamarkin et al. teaches embodiments of the microemulsion wherein the active agent is present in a concentration of 0.1%, 0.5, 1.0 and 5 (page 18, paragraph 331). Tamarkin et al. teaches teaches the emulsions are applied to the skin and mucosal surfaces (page 18, paragraph 318) which are cutaneous surfaces of a mammal and therefore describe percutaneous absorption,

which is absorption through unbroken skin, and are therefore capable of performing the intended recited in instant claim 15.

Tamarkin et al. does not specifically teach the composition wherein the aqueous phase is 0.5 to 2% by weight or comprising sodium hyaluronate having a molecular weight ranging from 50 to 200 kDa present in an amount ranging from 0.001 to 0.1 by weight (instant claim 1). Tamarkin et al. does not specifically teach the composition further comprising hyaluronic acid (instant claim 8). Tamarkin et al. does not specifically teach the composition comprising sodium hyaluronate as hyalastine (instant claim 16).

Friedman et al. discloses an oil-in-water emulsions wherein the emulsion further comprises a mucoadhesive polymer hyaluronic acid (abstract). Friedman et al. discloses the polymer hyaluronic acid may be present as free acids or salts (column 7, lines 16-17) with a preferred molecular weight of at least 50, 300, or 1,000 kDa (column 7, lines 54-56), and envisions mucoadhesive polymer treated with NaOH to give the sodium salt (column 10, lines 59-60). Friedman et al. teaches the preparation of the emulsion followed by addition of an aqueous solution, or acceptable carrier, containing the hyaluronic acid and excipients such as EDTA, preservatives, and antioxidants is within the level of ordinary skill in the art. Friedman et al. citing Riley Jr., US Patent 5,055,303, as prior art disclosing bioadherent emulsions of the water-in-oil type (column 2, lines 35-40) teaches it is within the level of ordinary skill in the art to apply the teaching of Friedman et al. to water-in-oil emulsions. Friedman teaches the bioadhesive polymer is present in the microparticle usually in a final concentration of 0.01% wt/vol. (column 7, lines 15-20).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Tamarkin et al. in view of Friedman et al. One of ordinary skill in the art would be motivated to combine Tamarkin et al. in view of Friedman et al. because Friedman et al. teaches bioadhesion is advantageous for drug delivery (Friedman et al. column 1, lines 15-65). One of ordinary skill in the art would have a reasonable expectation of success in combining Tamarkin et al. in view of Friedman et al. because Tamarkin et al. teaches said composition is compatible with hyaluronic acid (page 14, paragraph 235) and Friedman et al. teaches said bioadhesive polymer is found in the interface between the water and oil (figure 1D in drawing sheet 2) and that it is within the level of ordinary skill in the art to apply the teaching of Friedman et al. to water-in-oil emulsions. Regarding the concentration of the aqueous phase, the range 0.5% to 2% is encompassed by the range "less than about 10% by weight water" taught by Tamarkin et al., and generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical, see MPEP 2144.05 IIA. Based on evidence provided by della Valle (US Patent 5,925,626, cited in PTO-892), hyalastine appears to refer to any hyaluronic acid having a molecular weight from about 50,000 to about 100,000 (della Valle column 2, lines 45-60). Therefore, hyaluronic acid having a molecular weight of 50 kDa taught by Friedman et al. is deemed to be hyalastine.

Response to Applicant's Remarks:

Applicant's Remarks, filed 24 Jun 2009, have been fully considered and found not to be persuasive with regard to claim 3.

Support for the instant claims 1, 4-6 and 8-17 is found in foreign priority document ITALY MI2003A002019 at least at pages 5-7 of the translation of ITALY MI2003A002019. However, foreign priority document ITALY MI2003A002019 recites support for only alkyl esters of C_{10}-C_{22} fatty acids, for example at page 5, line 25. Therefore the foreign priority document ITALY MI2003A002019 does not disclose support for the full scope of instant claim 3, and cannot be relied upon to overcome the rejection of instant claim 3 over Tamarkin et al. in view of Friedman et al.

Allowable Subject Matter

Claims 1, 4-6 and 8-17 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: The closest prior art is Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record) in view of Riley, Jr. (US Patent 5,055,303, issued 08 Oct 1991, of record).

The teaching of Friedman et al. in view of Riley, Jr. is recited in the Office Action mailed 10 July 2008.

Friedman et al. in view of Riley, Jr. does not specifically disclose said emulsion wherein the aqueous phase is present at a concentration ranging from 0.5 to 2% by weight.

It would not have been obvious to one of ordinary skill in the art at the time of the invention to combine Friedman et al. in view of Riley, Jr. to give the emulsion wherein the aqueous phase is present at a concentration ranging from 0.5 to 2% by weight. As noted by Applicant in remarks filed 12 Jan 2009 at page 9, Friedman et al. teaches emulsions that contain more than 5% water. As noted by Applicant in remarks filed 12 Jan 2009 at page 10, in view of the teaching of Friedman et al. regarding concentration of water and type concentration of emulsifiers, Friedman et al. does not teach the ratio of water to lecithin concentration is 3. The instant application provides data indicating that said ratio is results effective at figure 1 and page 9 of the instant specification. MPEP 2144.05 II.B. provides “A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." Therefore Friedman et al. in view of Riley, Jr. does not teach or fairly suggest the instant invention as claimed.

The closest art is Tamarkin et al. (US Patent Application Publication 2005/0031547, filed 28 Apr 2004, cited in PTO-892) in view of Friedman et al. (US Patent 5,744,155, issued 28 Apr 1998, of record). The claim of foreign priority to foreign priority document ITALY MI2003A002019, filed 17 Oct 2003, is perfected and relied

upon to overcome the intervening reference Tamarkin et al., and Friedman et al. alone does not teach or fairly suggest all limitations of the claims.

Applicant's analysis of the priority of Tamarkin et al. at pages 9-10 of Remarks filed 24 Jun 2009 is persuasive. Provisional Application 60/492,385, filed 4 Aug 2003, from which intervening reference Tamarkin et al. claims priority, recites compositions comprising from 85-98% to 25-75% water at pages 2-3 and 35-38 as noted by Applicant. Provisional Application 60/530,015, filed 16 Dec 2003, from which intervening reference Tamarkin et al. claims priority, was filed after foreign priority document ITALY MI2003A002019, filed 17 Oct 2003. Friedman et al. alone does not teach or fairly suggest the instant invention as claimed as recited above.

Conclusion

No claim is currently in condition for allowance.

This Office Action details new grounds of rejection not necessitated by Amendment. Accordingly, this Office Action is Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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